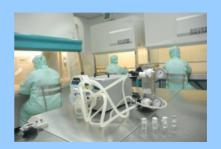
"Flu Vaccine Production by the Thai GPO: Economic Return VS National Security Concept – Balancing Sustainability and Cost-Effectiveness"

By

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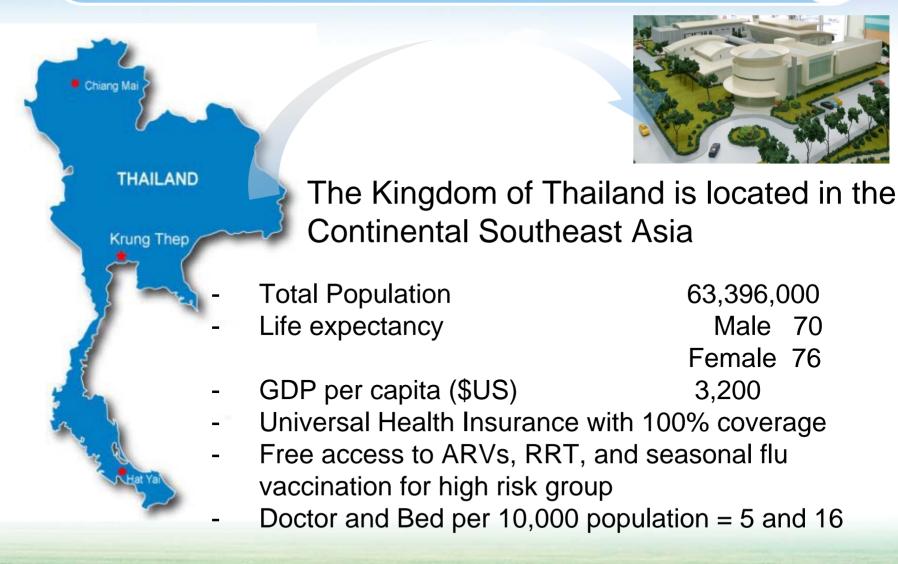








Introduction to the Kingdom of Thailand





Situation & Preparedness in Thailand

- ❖ 2004 Bird flu outbreak
- 2005 National Security Program has started for flu vaccine products in Thailand
- **2007-2009**
 - Thai Government allocated \$US 42 million for flu vaccine production project
 - WHO Collaboration for establishing R&D and flu vaccine production
 - -GPO takes responsible as project principle and investment for running the project

Situation of H1N1 in Thailand



% Thai people infected 12.6 - 15.8 Or approximately 8-10 million people (estmated on 30.11.09 by the Bureau of Epidemiology, MOPH, Thailand)

Cumulative numbers of patient cases 29,921

Cumulative numbers of death cases 192

Import of 2 million doses of PIIV at the cost of \$US 18 million – starts immunization today (11 **January 2010)** (Status ; Jan, 6, 2010)



Investment in Flu Vaccine Development & Production

(a) Pilot Plant - one BSL3 lab with GMP

Purpose: To build capacity on production & R&D of IIV and LAIV Capital investment since 2007, supported from:

- 1. WHO: \$US 4.05 million with support also from the USG
- 2. GPO: \$US 0.5 million for management & labor Cost

(b) Industrial-scale Plants – one IIV and one LAIV plant

Target: Adequate sustainable capacity to respond to Flu pandemic

- 2 to 10 million doses of Trivalent IIV annually
- 10 million doses of Trivalent LAIV annually

Capital investment supported from Thai Government :

- IIV plant \$US 42 million (2007-2011)
- LAIV plant \$US 8 million (2010-2012)







Rationale for Investment

- The principle rationale is "National Security"
 The additional purposes are to:
- Support "Sub-regional/Regional Security"
- Capacity building for self reliance

There is "no commercial purpose" – No concrete estimation of the return on investment at the beginning





Prepared local demand to sustain the factories

- The National Health Security Board approved seasonal flu vaccine coverage for the high risk groups since 2008 covering 4 million people within 3 years (2011)
- The IIV plant will start to produce this amount of vaccine in 2012 to respond to local demand. This will allow sustainability and continuity of the capacity





H1N1 2009 PLAIV Production

- a. Technology transfer: Pre-master seed from Institute of Experimental Medicine (IEM), Russia and production technology from WHO
- **b. Yield**: **15-20 doses/egg** (titer = $7.5 \log EID_{50}/0.5$ ml) current stock of around 1.5 million doses

c. Stability:

- Concentrated vaccine (-80°C) 12 weeks
- Finished vaccine in (-20 °C and 2-8 °C) 6 weeks

d. Clinical Trial:

- Phase I (part A) (toxicity test 24 subjects) 18
 December 2009 no immediate toxicity found
- Phase II (part B) (toxicity and immunogenicity 400 subjects) starts at the end of February 2010



Flu Vaccine Cost Comparison in Thailand

| Cost per dose vaccine (\$ US) | | | |
|-------------------------------|-----|----------------------|---------|
| Seasonal flu vaccine | | Pandemic flu vaccine | |
| Import | GPO | Import | GPO |
| 6 | 3.5 | 7.35 | ~1 |
| | | (IIV) | (PLAIV) |

Our Public Spirit on the Pandemic



- The GPO Board of Directors agreed to donate all H1N1 2009 PLAIV to the Thai government at no cost
- GPO committed to share 10% of PLAIV to WHO at no cost





Conclusion: Thanks to the Pandemic

- a. Thai government commitment to invest on flu vaccine
 R&D and production capacity in a sustainable manner.
- b. Commitment from international partners to support technology transfer to developing countries, including Thailand – WHO supported by USG, ADB, etc.
- c. Capacity building of the Thai GPO on the production of the Flu vaccine for "National Security" purpose.
- d. Increase access to seasonal Flu vaccine among Thais



Thank you for your attention